[to be date of distribution]

Urgent Product Correction Notice

Dear Valued bioMérieux Customer,

Our records indicate that you have received one of the following products.

Product Description: BacT/ALERT® 3D B.40.xx firmware

Description of issue:

BacT/ALERT® instrument software architecture is linearly designed to scan, process and load one bottle at a time. bioMérieux recently launched the new BacT/ALERT® 3D B.40.xx firmware that contains additional features such as bottle recalculation and bottle authentication. As a result of the additional features, customers with Control Modules containing LBC-586 CPUs, distributed from 1997 through November 2007, and running B.40 firmware may exhibit a slightly slower instrument interface issue that may result in bottles being improperly loaded into the instrument.

To aid the user when loading bottles, the instrument provides auditory feedback to indicate when bottles have been properly scanned. The BacT/ALERT User Manual does not clearly define the functionality of the audible beeps or the consequence if the proper loading sequence is not followed. The proper auditory sequence is two beeps after scanning the Bottle ID barcode and three beeps after scanning the Accession ID barcode. An improper load occurs when the user performs another action (such as loading a bottle or scanning another barcode) before the reply beep(s) have been issued. An improper load results in the first bottle not being recognized as being loaded in the instrument and the second bottle's readings being incorrectly reported in association with the first bottle. Improper loads of two bottles can occur multiple times when loading batches of bottles.

Impact to the Patient:

BacT/ALERT® Culture Bottles are used with the BacT/ALERT® Microbial Detection System in qualitative procedures for the recovery and detection of microorganisms (bacteria and yeast) from specimens including: blood and other normally sterile body fluids and processed or aseptically prepared products.

Customers who improperly load bottles may experience one or more of the following incorrect results from the instrument:

- No results for bottles not being recognized as being loaded in the instrument
- False negative or false positive results due to improper algorithm assignment
- Positive results reported on the wrong patient
- Negative results for a patient who may have a true positive result

Required actions:

We have modified our instructions for use to clarify how to properly load bottles and to provide appropriate cautions and warnings concerning bottle loading, especially in regards to the audible beep indicators. Pending introduction of new labeling, please review and implement the enclosed correction to the BacT/ALERT User Manual (Attachment B) when using the BacT/ALERT B.40 firmware.

We request you take the following actions at this time:

1. Ensure this letter and guidance in Attachment B on how to properly scan and load bottles into the BacT/ALERT 3D instrument is distributed, and training is provided to all appropriate personnel within your organization.
2. To check for lost bottles in your system:
   a) Identify all anonymous bottles following the Handling Anonymous Bottles procedures in the BacT/ALERT 3D User Manual.
   b) Ensure there are no anonymous bottles currently loaded in the instrument.
   c) Reboot the system following the Reboot/Shutdown procedure in your BacT/ALERT 3D User Manual.
   d) If anonymous bottles are detected as a result of the instrument reboot, remove the bottles from the instrument, immediately subculture the bottles, and call your bioMérieux representative to report the incident.
3. Fill out and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality products. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Thank you for your continued use of bioMérieux products,

[Enter Local Contact]

Attachments

Attachment A – Customer Acknowledgement Form
Attachment B – Supplementary Instructions For Use – Bottle Loading

Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA - 1494 - BacT/ALERT B.40 Firmware

Customer Information:

Customer Account Number: _____ Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name: _____

Contact Title: _____

Phone Number: _____

Product Information:

Catalog Number	Description
210147, 210148	BacT/ALERT® Control Module
200290, 200291, 247013, 247014	BacT/ALERT® Combo Module
411814, 411815, 411816, 411818, 411925, 411956, 411957, 411958, 412002, 412003, 412004, 412005, 412006, 412007, 412559, 412620, 412621, 412622, 412623, 412624, 412625, 412626, 412950, 412951, 413481, 413482, 413483, 413484	BacT/ALERT® B.40 Upgrade

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Questions:

	Yes	No
1. Did you read the enclosed Urgent Product Correction Notice **(P/N 60-00827-0)** regarding BacT/ALERT B.40 Firmware and the BacT/ALERT User Manual?		
2. Have you followed the instructions and implemented the actions as indicated in this Urgent Product Correction Notice?		
3. Have you received reports of injury to patient, unnecessary medical procedure or delay in a necessary medical procedure related to the BacT/ALERT B.40 Firmware and the BacT/ALERT User Manual?		
Comments:		

Signature: _____ Date: _____

It is important that you complete this Acknowledgement Form and return it to bioMérieux.

Please fax this form to: **[Enter Local Contact]** To the attention of: **[Enter Local Contact]**

BacT/ALERT® 3D Version B.40
Customer Communication

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The following information about the release of the new BacT/ALERT® 3D Version B.40 firmware is not contained in any of the user documentation. Please read all information provided and consult your local bioMérieux representative for further information.

BacT/ALERT® 3D System

The following paragraphs from the *BacT/ALERT® 3D Version B.40 User Manual, part number 411205,* require an update to add clarification concerning loading bottles using the barcode scanner.

Note: *Text that is revised is indicated by a change bar in the margin.*

Using the Barcode Scanner to Enter Data (Clinical Use)

When loading bottles using a barcode scanner, the instrument provides audible beeps as acknowledgement of steps. The barcode scanner beeps once when a barcode is read. The instrument issues one additional reply beep when the instrument has successfully completed processing the barcode information for a Bottle ID. The instrument will reply with two beeps when an Accession ID barcode has been successfully processed. The two beeps (one for the read and one reply) for Bottle ID and three beeps (one for the read and two replies) for Accession Number indicate the system has successfully scanned and processed the information. An improper load occurs when the user performs another action (such as loading a bottle or scanning another barcode) before the reply beep(s) have been issued. When incorrectly loading more than one bottle without waiting for the audible beeps to complete, the first bottle will not be recognized as being loaded in the instrument, and the second bottle's readings will be incorrectly reported in association with the first bottle.

CAUTION: In order to preserve test data integrity, handle only one bottle at a time. Completely load a bottle according to this procedure before proceeding to the next bottle. If using a barcode scanner, wait for all beeps to complete prior to loading the bottle into the instrument to ensure bottles are properly loaded.

To scan a bottle or accession barcode:

1. Before scanning the barcode, touch the desired field to place focus on that field. The field should turn white, indicating focus.
2. Rotate the bottle so the Bottle ID or Accession Number barcode is on top.
3. Place the bottle over the barcode strip located in the Barcode Reader Aperture below the Control Panel of the Controller Module (see Figure 2-2, Instrument Front View) or at the base of the barcode reader stand with the Combination Module (see Figure 2-6, Front View Combination Module).
4. There will be two short beeps when the Bottle ID is successfully scanned into the **Bottle ID** field.
5. If the **Accession Number** field is enabled, there will be three short beeps when the Accession Number is successfully scanned into the **Accession Number** field.

If an Operator Error occurs, a series of beeps will alert the operator to view the Operator Panel.

If the barcode is not read:

1. Verify the appropriate field has focus.
2. Move the bottle away from the barcode strip and initiate another scan.

Note: *The **Hospital ID** field is a keyboard-entry field only.*

Loading Bottles (Clinical Use)

CAUTION: In order to preserve test data integrity, handle only one bottle at a time. Completely load a bottle according to this procedure before proceeding to the next bottle. If using a barcode scanner, wait for all beeps to complete prior to loading the bottle into the instrument to ensure bottles are properly loaded.

WARNING

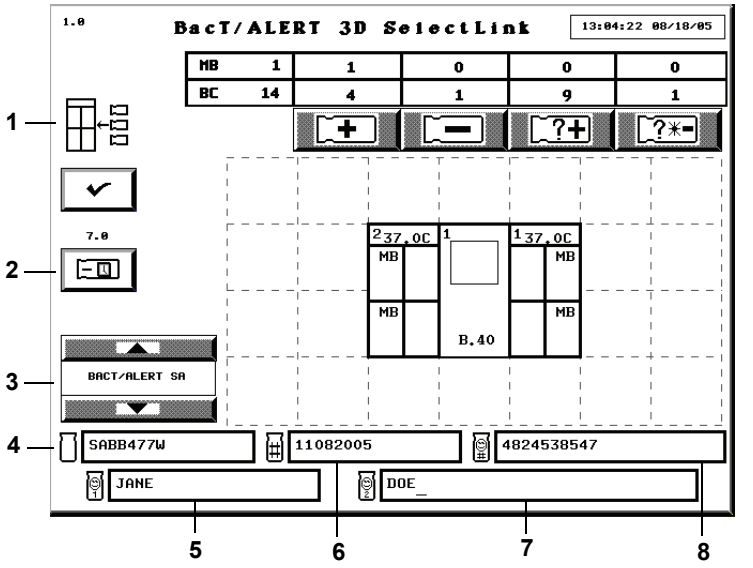
An improper load could occur if the series of beeps do not finish before the bottle is loaded into the instrument. Improperly loaded bottles will experience no results, misidentified/incorrect results, or false negative results due to the bottles being read on the incorrect algorithm.

CAUTION: Only bottles provided by bioMérieux are authorized for use with the BacT/ALERT® 3D system. bioMérieux shall not be liable as to any defect (including, but not limited to, incorrect results that may affect patient outcomes) arising from the use of unauthorized bottles. Customers who use bottles not authorized by bioMérieux do so at their own risk.

1. From the Main screen (see Figure 3-1), press the **Load Bottles** button ( ).

   The Load Mode screen appears.

Figure 3-7: Main Screen — Load Mode



1 — Load Bottles Icon
2 — Change Maximum Test Time Button
3 — Bottle Type Scroll Button
4 — Bottle ID Field
5 — Patient First Name Field*
6 — Accession Number Field
7 — Patient Last Name Field*
8 — Hospital ID Field*

*Available with Select and SelectLink only

The number of available cells appears at the bottom of each drawer on the **Instrument** icon.

Green indicators on Incubation or Combination Module drawers illuminate drawers that contain available cells.

CAUTION: Inspect each bottle and sensor before loading:
If the sensor is yellow, treat the bottle as a positive culture. If the bottle is cracked, do not load the bottle.

2. Verify the **Bottle ID** field appears white. Then scan or manually enter the Bottle ID (see Text/Data Entry on page 3-7). If scanning, wait for the second beep to sound before continuing.

   If the field is left blank when a bottle is loaded, then the bottle is considered anonymously loaded (see Handling Anonymous Bottles on page 3-12).

3. Verify the correct bottle type is displayed on the **Bottle Type** scroll button.

If the **Bottle ID** field contains data from a generic label, the bottle type can be manually entered using the **Bottle Type** scroll button before inserting the bottle to ensure proper testing of the bottle. The instrument will also beep continuously to alert the operator that the bottle type needs to be manually entered. The audible alert can be disabled by calling bioMérieux for assistance. See Figure 3-7.

CAUTION: For best results, manually enter the bottle type when "GENERIC" is the displayed bottle type. Otherwise, observe the following:

- **When a bottle is loaded with a generic or anonymous bottle type, care must be taken to load BacT/ALERT® MP bottles into drawers labeled MB. The maximum test time assigned to a generic bottle loaded into an MB drawer is the same time assigned to the BacT/ALERT® MP media type in the Set Maximum Test Time screen (see Setting the Maximum Test Time in Chapter 7).**
- **All non-MB bottles must be loaded into drawers labeled BC and the maximum test time is set to the time specified for the Unknown bottle type.**
- **BacT/ALERT® MB Bottles should never be loaded with a Generic media type or loaded anonymously. BacT/ALERT® MB must be displayed on the Bottle Type scroll button before loading a BacT/ALERT® MB bottle.**

4. If the **Accession Number** field is enabled and blank, then continue to Step 5. If the **Accession Number** field is disabled, then go to Step 7.
5. Verify the **Accession Number** field appears white. Then scan or manually enter the *accession number*. If scanning, wait for the third beep to sound before continuing.

Note: *An Accession Number cannot begin with a **$** followed by a ten-digit number.*

Using the Barcode Scanner to Enter Data (Industry Use)

When loading bottles using a barcode scanner, the instrument provides audible beeps as acknowledgement of steps. The barcode scanner beeps once when a barcode is read. The instrument issues one additional reply beep when the instrument has successfully completed processing the barcode information for a Bottle ID. The instrument will reply with two beeps when a Sample ID barcode has been successfully processed. The two beeps (one for the read and one reply) for Bottle ID and three beeps (one for the read and two replies) for Sample Number indicate the system has successfully scanned and processed the information. An improper load occurs when the user performs another action (such as loading a bottle or scanning another barcode) before the reply beep(s) have been issued. When incorrectly loading more than one bottle without waiting for the audible beeps to complete, the first bottle will not be recognized as being loaded in the instrument, and the second bottle's readings will be incorrectly reported in association with the first bottle.

CAUTION: In order to preserve test data integrity, handle only one bottle at a time. Completely load a bottle according to this procedure before proceeding to the next bottle. If using a barcode scanner, wait for all beeps to complete prior to loading the bottle into the instrument to ensure bottles are properly loaded.

To scan a bottle or sample barcode:

1. Before scanning the barcode, touch the desired field to place focus on that field. The field should turn white, indicating focus.
2. Rotate the bottle so the Bottle ID or Sample ID barcode is on top.
3. Place the bottle over the barcode strip located in the Barcode Reader Aperture below the Control Panel of the Controller Module (see Figure 2-2, Instrument Front View) or at the base of the barcode reader stand with the Combination Module (see Figure 2-6, Front View Combination Module).
4. There will be two short beeps when the Bottle ID is successfully scanned into the **Bottle ID** field.
5. If the **Sample ID** field is enabled, there will be three short beeps when the Sample ID is successfully scanned into the **Sample ID** field.

If an Operator Error occurs, a series of beeps will alert the operator to view the Operator Panel.

If the barcode is not read:

1. Verify the appropriate field has focus.
2. Move the bottle away from the barcode strip and initiate another scan.

*The **User Defined 3** field is a keyboard-entry field only.*

Loading Bottles (Industry Use)

CAUTION: In order to preserve test data integrity, handle only one bottle at a time. Completely load a bottle according to this procedure before proceeding to the next bottle. If using a barcode scanner, wait for all beeps to complete prior to loading the bottle into the instrument to ensure bottles are properly loaded.

WARNING

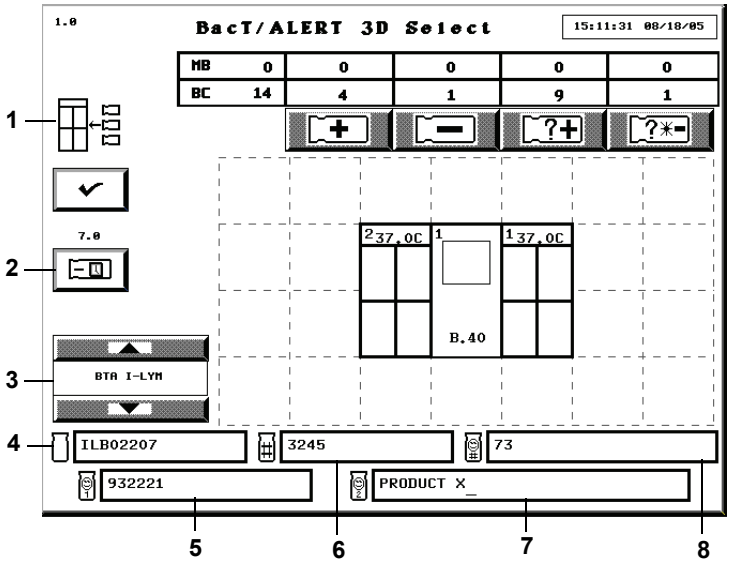
An improper load could occur if the series of beeps do not finish before the bottle is loaded into the instrument. Improperly loaded bottles will experience no results, misidentified/incorrect results, or false negative results due to the bottles being read on the incorrect algorithm.

CAUTION: Only bottles provided by bioMérieux are authorized for use with the BacT/ALERT® 3D system. bioMérieux shall not be liable as to any defect (including, but not limited to, incorrect results that may affect patient outcomes) arising from the use of unauthorized bottles. Customers who use bottles not authorized by bioMérieux do so at their own risk.

1. From the Main screen (see Figure 4-1), press the **Load Bottles** button ( ).

   The Load Mode screen appears.

Figure 4-7: Main Screen — Load Mode



1 — Load Bottles Icon
2 — Change Maximum Test Time Button
3 — Bottle Type Scroll Button
4 — Bottle ID Field
5 — User Defined 1 Field*
6 — Sample ID Field
7 — User Defined 2 Field*
8 — User Defined 3 Field*

*Available with Select and SelectLink only

The number of available cells appears at the bottom of each drawer on the **Instrument** icon.

Green indicators on Incubation or Combination Module drawers illuminate drawers that contain available cells.

CAUTION: Inspect each bottle and sensor before loading:
If the sensor is yellow, treat the bottle as a positive culture. If the bottle is cracked, do not load the bottle.

2. Verify the **Bottle ID** field appears white. Then scan or manually enter the Bottle ID (see Text/Data Entry on page 4-7). If scanning, wait for the second beep to sound before continuing.

   If the field is left blank when a bottle is loaded, then the bottle is considered anonymously loaded (see Handling Anonymous Bottles on page 4-11).

3. Verify the correct bottle type is displayed on the **Bottle Type** scroll button.

If the **Bottle ID** field contains data from a generic label, the bottle type can be manually entered using the **Bottle Type** scroll button before inserting the bottle to ensure proper testing of the bottle. The instrument will also beep continuously to alert the operator that the bottle type needs to be manually entered. The audible alert can be disabled by calling bioMérieux for assistance. See Figure 4-7.

4. If the **Sample ID** field is enabled and blank, then continue to Step 5. If the **Sample ID** field is disabled, then go to Step 7.
5. Verify the **Sample ID** field appears white. Then scan or manually enter the *sample ID*. If scanning, wait for the third beep to sound before continuing.

Note: *A Sample ID number cannot begin with a **$** followed by a ten-digit number.*

BacT/ALERT® 3D 60 System

The following paragraphs from the *BacT/ALERTD® 3D 60 Version B.40 User Manual, part number 411329,* require an update to add clarification concerning loading bottles using the barcode scanner.

Note: *Text that is revised is indicated by a change bar in the margin.*

Using the Barcode Scanner to Enter Data

When loading bottles using a barcode scanner, the instrument provides audible beeps as acknowledgement of steps. The barcode scanner beeps once when a barcode is read. The instrument issues one additional reply beep when the instrument has successfully completed processing the barcode information for a Bottle ID. The instrument will reply with two beeps when an Accession ID barcode has been successfully processed. The two beeps (one for the read and one reply) for Bottle ID and three beeps (one for the read and two replies) for Accession Number indicate the system has successfully scanned and processed the information. An improper load occurs when the user performs another action (such as loading a bottle or scanning another barcode) before the reply beep(s) have been issued. When incorrectly loading more than one bottle without waiting for the audible beeps to complete, the first bottle will not be recognized as being loaded in the instrument, and the second bottle's readings will be incorrectly reported in association with the first bottle.

CAUTION: In order to preserve test data integrity, handle only one bottle at a time. Completely load a bottle according to this procedure before proceeding to the next bottle. If using a barcode scanner, wait for all beeps to complete prior to loading the bottle into the instrument to ensure bottles are properly loaded.

To scan a bottle or accession barcode:

1. Before scanning the barcode, click the desired field to place focus on that field. The field should turn white indicating focus.
2. Rotate the bottle so the Bottle ID or Accession Number barcode is on top.
3. Place the bottle over the barcode strip located at the base of the barcode reader stand (see Figure 2-2, Instrument Front View).
4. There will be two short beeps when the Bottle ID is successfully scanned into the **Bottle ID** field.

5. If the **Accession Number** field is enabled, there will be three short beeps when the Accession Number is successfully scanned into the **Accession Number** field.

If an Operator Error occurs, a series of beeps will alert the operator to view the Operator Panel.

If the barcode is not read:

1. Verify the appropriate field has focus.
2. Move the bottle away from the barcode strip and initiate another scan.

Note: *The **Hospital ID** field is a keyboard-entry field only.*

Loading Bottles

CAUTION: In order to preserve test data integrity, handle only one bottle at a time. Completely load a bottle according to this procedure before proceeding to the next bottle. If using a barcode scanner, wait for all beeps to complete prior to loading the bottle into the instrument to ensure bottles are properly loaded.

WARNING

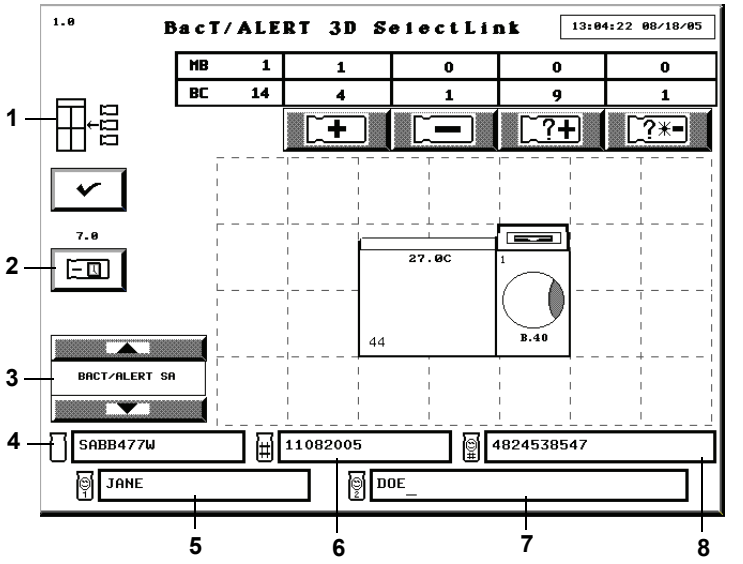
An improper load could occur if the series of beeps do not finish before the bottle is loaded into the instrument. Improperly loaded bottles will experience no results, misidentified/incorrect result, or false negative results due to the bottles being read on the incorrect algorithm.

CAUTION: Only bottles provided by bioMérieux are authorized for use with the BacT/ALERT® 3D system. bioMérieux shall not be liable as to any defect (including, but not limited to, incorrect results that may affect patient outcomes) arising from the use of unauthorized bottles. Customers who use bottles not authorized by bioMérieux do so at their own risk.

1. From the Main screen (see Figure 4-1), press the **Load Bottles** button ( ).

   The Load Mode screen appears.

Figure 4-6: Main Screen — Load Mode



1 — Load Bottles Icon
2 — Change Maximum Test Time Button
3 — Bottle Type Scroll Button
4 — Bottle ID Field
5 — Patient First Name Field*
6 — Accession Number Field
7 — Patient Last Name Field*
8 — Hospital ID Field*
9 — Cells Available for Loading

The number of available cells appears at the bottom left hand side of the **Instrument** icon.

CAUTION: Inspect each bottle and sensor before loading:
If the sensor is yellow, treat the bottle as a positive culture. If the bottle is cracked, do not load the bottle.

2. Verify the **Bottle ID** field appears white. Then scan or manually enter the Bottle ID (see Text/Data Entry on page 4-5). If scanning, wait for the second beep to sound before continuing.

   If the field is left blank when a bottle is loaded, then the bottle is considered anonymously loaded (see Handling Anonymous Bottles on page 4-11).

3. Verify the correct bottle type is displayed on the **Bottle Type** scroll button.

   If the **Bottle ID** field contains data from a generic label, the bottle type can be manually entered using the **Bottle Type** scroll button before inserting the bottle to ensure proper testing of the bottle. The instrument will also

beep continuously to alert the operator that the bottle type needs to be manually entered. The audible alert can be disabled by calling bioMérieux for assistance. See Figure 4-6.

CAUTION: For best results, manually enter the bottle type when "GENERIC" is the displayed bottle type. Otherwise, observe the following:

- **When a bottle is loaded with a generic or anonymous bottle type, care must be taken to load BacT/ALERT® MP bottles into drawers labeled MB. The maximum test time assigned to a generic bottle loaded into an MB drawer is the same time assigned to the BacT/ALERT® MP media type in the Set Maximum Test Time screen (see Setting the Maximum Test Time in Chapter 6).**
- **All non-MB bottles must be loaded into drawers labeled BC and the maximum test time is set to the time specified for the Unknown bottle type.**
- **BacT/ALERT® MB Bottles should never be loaded with a Generic media type or loaded anonymously. BacT/ALERT® MB must be displayed on the Bottle Type scroll button before loading a BacT/ALERT® MB bottle.**

4. If the **Accession Number** field is enabled and blank, then continue to Step 5. If the **Accession Number** field is disabled, then go to Step 7.
5. Verify the **Accession Number** field appears white. Then scan or manually enter the *accession number*. If scanning, wait for the third beep to sound before continuing.

Note: *An Accession Number cannot begin with a **$** followed by a ten-digit number.*

BacT/ALERT® 3D Dual-T System

The following paragraphs from the *BacT/ALERT® 3D Dual-T Version B.40 User Manual, part number 411174,* require an update to add clarification concerning loading bottles using the barcode scanner.

Note: *Text that is revised is indicated by a change bar in the margin.*

Using the Barcode Scanner to Enter Data

When loading bottles using a barcode scanner, the instrument provides audible beeps as acknowledgement of steps. The barcode scanner beeps once when a barcode is read. The instrument issues one additional reply beep when the instrument has successfully completed processing the barcode information for a Bottle ID. The instrument will reply with two beeps when a Sample ID barcode has been successfully processed. The two beeps (one for the read and one reply) for Bottle ID and three beeps (one for the read and two replies) for Sample Number indicate the system has successfully scanned and processed the information. An improper load occurs when the user performs another action (such as loading a bottle or scanning another barcode) before the reply beep(s) have been issued. When incorrectly loading more than one bottle without waiting for the audible beeps to complete, the first bottle will not be recognized as being loaded in the instrument, and the second bottle's readings will be incorrectly reported in association with the first bottle.

CAUTION: In order to preserve test data integrity, handle only one bottle at a time. Completely load a bottle according to this procedure before proceeding to the next bottle. If using a barcode scanner, wait for all beeps to complete prior to loading the bottle into the instrument to ensure bottles are properly loaded.

To scan a bottle or sample ID barcode:

1. Before scanning the barcode, touch the desired field to place focus on that field. The field should turn white, indicating focus.
2. Rotate the bottle so the Bottle ID or Sample ID barcode is on top.
3. Place the bottle over the barcode strip located in the Barcode Reader Aperture below the Control Panel of the Controller Module (see Figure 2-2) or at the base of the barcode reader stand with the Combination Module (see Figure 2-6).

4. There will be two short beeps when the bottle ID is successfully scanned into the **Bottle ID** field.
5. If the **Sample ID** field is enabled, there will be three short beeps when the Sample ID is successfully scanned into the **Sample ID** field.

If an Operator Error occurs, a series of beeps will alert the operator to view the Operator Panel.

If the barcode is not read:

1. Verify the appropriate field has focus.
2. Move the bottle away from the barcode strip and initiate another scan.

*The **User Defined 3** field is a keyboard-entry field only.*

Loading Bottles

CAUTION: In order to preserve test data integrity, handle only one bottle at a time. Completely load a bottle according to this procedure before proceeding to the next bottle. If using a barcode scanner, wait for all beeps to complete prior to loading the bottle into the instrument to ensure bottles are properly loaded.

WARNING

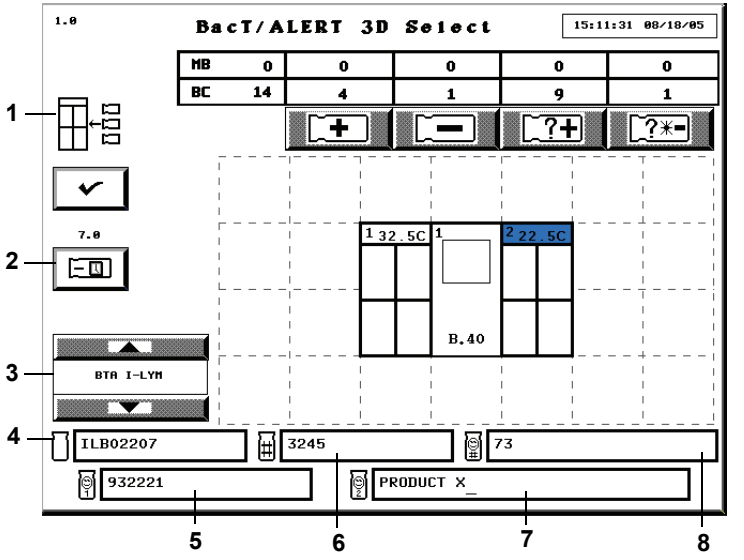
An improper load could occur if the series of beeps do not finish before the bottle is loaded into the instrument. Improperly loaded bottles will experience no results, misidentified/incorrect results, or false negative results due to the bottles being read on the incorrect algorithm.

CAUTION: Only bottles provided by bioMérieux are authorized for use with the BacT/ALERT® 3D system. bioMérieux shall not be liable as to any defect (including, but not limited to, incorrect results that may affect patient outcomes) arising from the use of unauthorized bottles. Customers who use bottles not authorized by bioMérieux do so at their own risk.

1. From the Main screen (see Figure 3-1), press the **Load Bottles** button ( ).

   The Load Mode screen appears.

Figure 3-8: Main Screen — Load Mode



1 — Load Bottles Icon
2 — Change Maximum Test Time Button
3 — Bottle Type Scroll Button
4 — Bottle ID Field
5 — User Defined 1 Field*
6 — Sample ID Field
7 — User Defined 2 Field*
8 — User Defined 3 Field*

*Available with Select and SelectLink only

The number of available cells appears at the bottom of each drawer on the **Instrument** icon.

Green indicators on Incubation or Combination Module drawers illuminate drawers that contain available cells.

CAUTION: Use care when opening Incubation Module or Combination Module drawers to avoid a tip over/crush hazard. Serious injury could result if drawers are opened with extreme force.

CAUTION: Inspect each bottle and sensor before loading:
If the sensor is yellow, treat the bottle as a positive culture. If the bottle is cracked, do not load the bottle.

WARNING

The BacT/ALERT® 3D Dual-T consists of the standard high temperature Incubation Module(s) that are used to test samples at 30°C to 35°C, and LT Module(s) that are used to test samples at 20°C to 25°C.

An erroneous test result (for example: false positive, false negative, delayed result) could occur if bottles are placed in an inappropriate temperature application.

2. Verify the **Bottle ID** field appears white. Then scan or manually enter the Bottle ID (see Text/Data Entry on page 3-8). If scanning, wait for the second beep to sound before continuing.

   If the field is left blank when a bottle is loaded, then the bottle is considered anonymously loaded (see Handling Anonymous Bottles on page 3-12).

3. Verify the correct bottle type is displayed on the **Bottle Type** scroll button.

   If the **Bottle ID** field contains data from a generic label, the bottle type can be manually entered using the **Bottle Type** scroll button before inserting the bottle to ensure proper testing of the bottle. The instrument will also beep continuously to alert the operator that the bottle type needs to be manually entered. The audible alert can be disabled by calling bioMérieux for assistance. See Figure 3-8.

4. If the **Sample ID** field is enabled and blank, then continue to Step 5. If the **Sample ID** field is disabled, then go to Step 7.
5. Verify the **Sample ID** field appears white. Then scan or manually enter the *sample ID*. If scanning, wait for the third beep to sound before continuing.

*A sample ID number cannot begin with a **$** followed by a ten-digit number.*